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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,987

Applicant(s)

BEUCKELEER, MARC DE

Examiner

Jehanne E Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 28-34 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied (necessitated by amendment) or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow.

This action is NON-FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 28-33 remain rejected and newly added claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to DNA molecules that result from amplification using primers. With regard to claim 28, one primer comprises a sequence of 15-30 nucleotides that is

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complementary to a sequence within SEQ ID NO: 6 or SEQ ID NO: 10. It is noted that due to the word “comprising” such primer can have any sequence on either side of the 15-30 nucleotides that are complementary to SEQ ID NO: 6 or SEQ ID NO: 10. Claim 28 also recites that the second is complementary to foreign DNA present in GAT-ZM1. This recitation does not limit the primer sequence to any particular nucleic acid sequence because the term GAT-ZM1 is not limited to a single event in a single strain of corn. Therefore, the claim is broadly drawn to a nucleic acid that can be amplified by a primer with a small degree of complementarity to SEQ ID NO: 6 or 10 and a primer with no defined sequence. Such a DNA molecule encompasses an extremely large number of DNA molecules, which include genomic DNA, genes, or fragments, from any corn plant, that have not been taught or described in the specification. The teachings of SEQ ID NO: 6 or SEQ ID NO: 10 are not representative of this extremely large genus of nucleic acids. With regard to claim 34, the limitation of the second primer to contain a region with complementarity to SEQ ID NO: 6 or SEQ ID NO: 10, does not limit the genus of nucleic acids that could be amplified by such primers to sequences taught or described in the specification. With regard to claim 32, such claim reads on any nucleic acid molecule that comprises SEQ ID NO: 6 or SEQ ID NO: 10 which encompasses nucleic acids of unlimited size which contain undisclosed genomic DNA as well as “foreign DNA”. With regard to claims 29, 30, and 33, although these claims contain limitations as to primer sequences with specific SEQ ID NOS or regions of SEQ ID NOS, such claims still read on an extremely large genus of nucleic acids, including undisclosed genomic DNA, whole genes, and fragments thereof, that have not been taught or described in the specification. The claims are not limited to a specific corn plant (ie: a specific strain), wherein large amounts of variability exist in such plants such that the genus of

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nucleic acids encompassed by the claims is extremely large. Further, it is well known that non-specific amplification results from PCR, for example, wherein DNA molecules are amplified that are not completely complementary to the primers used for amplification. The instantly pending claims thus encompass a large genus of non-specifically amplified DNA sequences as well.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 6 and 10, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d

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1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

5. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession number A17373 (April 1994).

A17373 teaches a sequence from SEQ ID NO: 10, which is part of an artificial pat gene. Such a sequence could be amplified by a primer which is complementary to a sequence within SEQ ID NO: 10 and a primer complementary to foreign DNA. The term "foreign" DNA has been broadly interpreted to encompass a sequence which is 'foreign' to the corn plant, which encompasses sequences within the artificial pat gene taught by accession number A17373.

Claim Rejections - 35 USC § 103

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Accession number A17373 in view of Ahern.

A17373 teaches a sequence from SEQ ID NO: 10, which is part of an artificial pat gene. Such a sequence could be amplified by a primer which is complementary to a sequence within SEQ ID NO: 10 and a primer complementary to foreign DNA. The term "foreign" DNA has

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been broadly interpreted to encompass a sequence which is 'foreign' to the corn plant, which encompasses sequences within the artificial pat gene taught by accession number A17373.

Accession number A17373 does not teach the DNA in kit format, however Ahern teaches that kits with premade biochemicals and reagents offer scientists the opportunity to better manage their time (see p. 4, lines 1-2). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the artificial pat gene taught by the accession number in kit format for the purpose of providing the gene in a readily accessible format to save researchers time in assays requiring the gene.

Conclusion

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Primary Examiner
Art Unit 1634

Jehanne Souaya
8 Aug. 4, 2003